

**§ 120.3 Definitions.**

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, §101.9(j)(18)(vi), and part 110 of this chapter are applicable to such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with §120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under

control and to produce an accurate record for use in verification.

(j)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and

(ii) The operation of a retail establishment.

(k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

**§ 120.5 Current good manufacturing practice.**

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the